# Accuracy of duplex sonography scans after renal artery stenting

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***Purpose:*** **Reports of duplex sonography scan criteria for recurrent renal arterial (RA) stenosis after endoluminal stenting have suggested that criteria for native arteries may overestimate recurrent disease. This retrospective report examines the utility of renal duplex sonography (RDS) scans to define the presence of significant (ie, ≥60%) renovascular disease (RVD) after percutaneous angioplasty and endoluminal stenting (PTAS).**

***Methods:*** **Demographic, duplex, and angiographic data were reviewed and compared. RDS was obtained. Peak systolic velocities (PSV) were obtained after PTAS from multiple sites along the main RA from both anterior and flank approaches. Comparable images from digital subtraction angiography were independently examined for restenosis. Percent diameter stenosis was determined from the site of maximal stenosis compared with the normal RA distal to the stent. Sensitivity and specificity were estimated and 95% confidence intervals (CIs) were computed after adjusting for within patient "clustering" of observations applying native RA RDS criteria using angiography as the gold standard. Receiver operating characteristic (ROC) curves were used to estimate the optimal RDS values for recurrent stenosis.**

***Results:*** **From October 2003 to June 2009, 49 patients had angiographic imaging after PTAS. There were 30 patients (18 women, 12 men; mean age, 71 ± 9 years) provided technically adequate paired angiographic and RDS assessment after PTAS for 66 RAs. Paired analysis was performed for 23 RAs after primary PTAS and 43 RAs after secondary treatment. The prevalence of significant restenosis was 35% (23 of 66 RAs). RAs with greater than 60% diameter restenosis had higher peak systolic velocity (PSV) compared to those without (2.48 ± 1.15 millisecond vs 1.44 ± 0.58 millisecond; $P < .001$). Compared to angiography, RA-PSV ≥1.8 millisecond with distal RA turbulence demonstrated a sensitivity of 73% (95% CI, 54%, 91%), specificity of 80% (95% CI, 67%, 93%), and an overall accuracy of 77% (95% CI, 67%, 88%) with a positive predictive value of 64% (95% CI, 46%, 82%). Optimal RDS value estimated by ROC curve resulted in RA-PSV of 2.5 millisecond which was associated with a sensitivity of 59% (95% CI, 36%, 82%), specificity of 95% (95% CI, 89%, 100%), an accuracy of 83% (95% CI, 74%, 92%), and a positive predictive value of 87% (95% CI, 68%, 100%).**

***Conclusion:*** **Renal duplex sonography has utility to detect significant restenosis after PTAS. RDS criteria for significant native RA stenosis compare favorably with optimal RDS criteria for restenosis estimated by ROC curves. (J Vasc Surg 2010;52:953-8.)**

Renal duplex sonography (RDS) scan has proven clinical use in the management of atherosclerotic renovascular disease (RVD). At our center, RDS is the screening method of choice for RVD contributing to hypertension and/or excretory renal insufficiency (ie, ischemic nephropathy).[1] RDS has also proven utility as an intraoperative completion study after open operative repair.[2] Moreover, RDS accurately defines patency, restenosis, and occlusion in follow-up after operative repair of RVD.[3] In addition to evaluation for clinical disease, RDS has defined the prevalence of RVD in a large, free-living group of elderly participants and defined the rate of anatomic progression in this group on follow-up.[4]

Despite the value of RDS in screening, intraoperative assessment, and postoperative surveillance after open operative repair, recent studies have questioned the utility of RDS after percutaneous angioplasty and endoluminal stenting (PTAS) for RVD.[5,6] These studies suggest that velocity criteria accurate for native RVD are associated with unacceptable rates of false-positive studies when applied after PTAS. Compliance change of the renal artery (RA) wall after placement of an endoluminal stent is most frequently cited for false-positive studies after PTAS. Several studies exist examining this phenomenon in the carotid literature, however, very little data are available regarding duplex scan velocities after renal PTAS.

The specific aim of this study was to examine RDS parameters that best correlate with hemodynamically significant restenosis after RA PTAS defined by digital subtraction angiography (DSA).

## METHODS

**Patient population.** All patients underwent RA-PTAS for RA atherosclerosis and severe hypertension, with or with-

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out renal dysfunction. All patients had temporal digital subtraction angiograms that could be interpreted for restenosis. Patients treated with RA-PTAS for fibromuscular dysplasia were excluded from this study. The study was conducted with the approval of the Wake Forest University Health Sciences Institutional Review Board.

All procedures were performed by vascular surgeons at Wake Forest University School of Medicine between October 2003 and June 2009. Procedural preparation, procedural management, and follow-up for patients treated with RA-PTAS at our center have been described in detail previously.[1] Follow-up angiograms were performed during intervention for restenosis (35%), contralateral RA intervention (55%), or aortic endografting (10%). RDS was performed before RA intervention and within 24 hours after each RA-PTAS. Thereafter, routine RDS surveillance was performed at 1-, 4-, and 6-month intervals.

**Data collection and management.** Patient demographics, comorbidities, and all relevant clinical information were retrospectively collected from the electronic medical records. A faculty vascular surgeon, blinded to the study, reviewed all angiographic data in a retrospective fashion for technical adequacy. Second and third individuals (vascular surgery fellows), blinded to the study, reviewed the images and calculated percent stenosis. Intraclass correlation was calculated between the two observers. RDS data, including peak systolic velocity (PSV), resistive index, and kidney length were obtained from a prospectively maintained database.

**Renal angiography.** All angiograms and RA-PTAS were performed in a dedicated endosuite with a Siemens Axiom Artis unit (Malvern, Pa). Anteroposterior and left anterior oblique DSA was obtained with power injection through a pigtail catheter placed at the level of the RAs. All RVD was ostial in location and all RAs were stented primarily with either Cordis Genesis (29), Boston Scientific Biliary Express (Natick, Mass) (12), Boston Scientific Express (9), Transhepatic (4), Medtronic Racer (Santa Rosa, Calif) (2) or Cordis Aviator (Warren, NJ) (1) stents delivered over a 0.014-inch balloon-tipped wire inflated to provide distal embolic protection. Balloon-mounted stents were sized to match the diameter of the normal RA distal to the atherosclerotic lesion. Completion angiography was performed with both pressure and hand injection. In 72 of 91 interventions, pullout pressures were obtained to identify residual pressure gradients consistent with residual stenosis. Postprocessing of digital subtraction angiograms was performed by one of two dedicated registered radiology technologists and transferred to the electronic medical record. Peak opacification and pixel shift functions were used to maximize the RA contrast column. In peak opacification, several images (range, 2-6 images) from the source contrast injection were combined. Temporal DSA was used in all instances: mask images were obtained before contrast injection at a rate of one image per second. These images were then used as a reference for digital subtraction of bone and soft tissue during the arteriogram.

Degree stenosis was estimated from postprocessed angiograms using electronic calipers in IDXRAD software (Burlington, Vt). Percent stenosis was estimated by comparing the diameter of the smallest contrast column with the diameter of the normal lumen of the main RA distal to the lesion.

**Renal duplex sonography.** Each patient underwent RDS within 24 hours of the renal intervention, and again in 1, 4, and 6 months. Doppler ultrasound scan studies were performed using a 5.2-MHz curvilinear probe with Doppler color flow, with either a Phillips IU22 (Phillips Healthcare, Andover, Mass) or an ATL HDI 5000 (Advanced Technology Laboratories, Bothell, Wash) ultrasound scan system using a previously described technique.[1] PSV from the aorta and RA were recorded. Restenosis was defined as RA PSV $\geq$1.8 millisecond in a stented artery previously documented as free of stenosis by completion angiography and RDS after PTAS.

**Statistical methods.** Descriptive statistics (frequencies and percentages for categorical characteristics; means, and SDs of continuous characteristics) were computed for patients included in evaluation of ultrasound scan prediction of RA restenosis. Receiver operating characteristic (ROC) curves were used to select an optimal cut point in RA PSV to predict restenosis $\geq$60% diameter reduction of stented renal arteries. Some contributed multiple arteries to the analyses; thus, methods were used to correct for potential within-subject correlation when calculating sensitivity and specificity estimates.[7] Proportional hazards regression models were used to evaluate potential predictors of restenosis after PTAS including 1- to 4-month postoperative change in ipsilateral artery PSV as a potential predictor of patency failure. All analyses were performed using SAS, version 9.2, software (SAS Institute Inc, Cary, NC).

## RESULTS

From October 2003 to June 2009, 49 patients had angiographic imaging after PTAS. Thirty patients provided technically adequate paired angiographic and RDS assessment after PTAS for 66 RAs. Each of the archived images were reviewed and interpreted for technical adequacy for interpretation. Nineteen studies were omitted due to poor contrast enhancement of the renal arteries (often studies performed for other reasons such as lower extremity occlusive disease), or inadequate projections for interpretation of stenosis. Intraclass correlation was calculated between the two image reviewers and found to be 85.7%. Demographic data are summarized in the Table. Sixty percent of the patients were male, 88% were white with an average age of 71 $\pm$ 9 years. All patients had severe hypertension and were on an average of 2.8 antihypertensive medications.

Last RA-PSV before PTAS averaged 2.75 $\pm$ 0.97 milliseconds. RA-PTAS measured within 24 hours after PTAS averaged 1.44 $\pm$ 0.83 milliseconds. RA-PSV within 24 hours after PTAS did not differ with the presence or absence of subsequent restenosis on follow-up (1.38 $\pm$ 0.70 milliseconds vs 1.53 $\pm$ 1.04 milliseconds; $P = .650$). The average RA to aorta pressure gradient after PTAS was 0.4 $\pm$

**Table.** Demographics

| *Variable* | *No. (%)* |
|---|---|
| Age, y | 70.4 |
| White race | 44 (88) |
| Female | 17 (34) |
| Smoking | |
| Never | 9 (18) |
| Former | 23 (46) |
| Current | 18 (36) |
| Diabetes | 20 (40) |
| Stroke | 15 (30) |
| Coronary artery disease | 24 (48) |
| COPD | 7 (14) |
| Left ventricular hypertrophy (ECG) | 8 (16) |
| Preop creatinine | 1.53 |
| Antihypertensive agents | 2.8 |
| Preop renal artery PSV, cm/s | 220 |
| Preintervention medications | |
| ACE inhibitor or ARB | 14 (28) |
| Beta-blocker | 36 (72) |
| Calcium channel blocker | 32 (64) |
| Diuretic | 26 (52) |
| Aspirin | 39 (78) |
| Clopidogrel | 10 (20) |
| Statin | 25 (50) |

*ACE,* Angiotensin converting enzyme; *ARB,* angiotensin II receptor blocker; *COPD,* chronic obstructive pulmonary disease; *ECG,* electrocardiogram; *PSV,* peak systolic velocity.

1.9 mm Hg (range, 0-10 mm Hg). All pullout pressures demonstrated zero gradients from RA to aorta for subjects with comparative RDS and angiograms on follow-up.

Paired analysis for RDS compared to angiography was performed for 23 RAs after primary PTAS and 43 RAs after secondary treatment. All secondary treatments of restenosis consisted of angioplasty alone (there were no instances of a second stent placement). The prevalence of restenosis after PTAS was 35% (23 of 66 RAs). All restenosis occurred within the previously placed stent. There were two false-negative results, both of which occurred in patients found angiographically to have multiple renal arteries. RAs with greater than 60% diameter restenosis had higher PSV compared to those without (2.48 ± 1.15 milliseconds vs 1.44 ± 0.58 milliseconds; $P < .001$). Fig 1 compares results from RDS with DSA. Compared to angiography, RA-PSV ≥1.8 milliseconds demonstrated a sensitivity of 73% (95% confidence interval [CI], 54%, 91%), specificity of 80% (95% CI, 67%, 93%), and an overall accuracy of 77% (95% CI, 67%, 88%) with a positive predictive value of 64% (95% CI, 46%, 82%). RA-PSV ≥2.0 milliseconds demonstrated a sensitivity of 68% (95% CI, 51%, 85%), specificity of 80% (95% CI, 67%, 93%), an accuracy of 76% (95% CI, 66%, 85%), and a positive predictive value of 63% (95% CI, 45%, 80%). Optimal RDS value estimated by ROC curve, demonstrated in Fig 2, resulted in RA-PSV of 2.5 milliseconds which was associated with a sensitivity of 59% (95% CI, 36%, 82%), specificity of 95% (95% CI, 89%, 100%), an accuracy of 83% (95% CI, 74%, 92%), and a positive predictive value of 87% (95% CI, 68%, 100%).

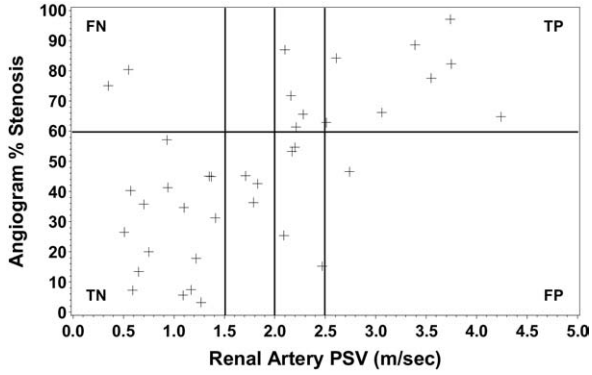


**Fig 1.** Receiver operating characteristic curve for renal artery peak systolic velocity (*PSV*) to predict recurrent ≥60% diameter reducing restenosis. *FN,* False negative; *TP,* true positive.

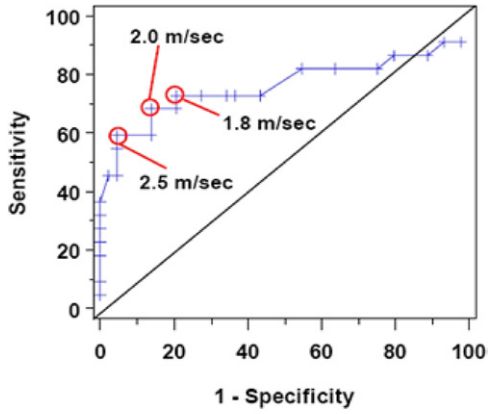


**Fig 2.** Scatter plot for renal artery peak systolic velocity (PSV; milliseconds) vs percent diameter reducing stenosis by angiography.

Proportional hazard regression models failed to identify independent predictors of restenosis after PTAS for this patient cohort.

## DISCUSSION

Although widely applied, the blood pressure and renal function benefit of RA PTAS for RVD is uncertain. Three small prospective studies comparing best medical management and PTAS failed to demonstrate a clear benefit from intervention.[8-10] Results from several large, ongoing randomized clinical trials comparing PTAS and medical management are expected in the near future. In this regard, the Angioplasty and Stent for Renal Artery Lesions (ASTRAL) has been one of the first of these trials to provide published results.[11] This multicenter trial randomized 806 patients with RVD to either primary renal PTAS or medical management. On median follow-up of 34 months, PTAS demonstrated no benefit on the rate of renal function decline, blood pressure, renal events, vascular events, or mortality. Unfortunately, the ASTRAL trial did not report the rate of restenosis among subjects randomized to PTAS.

A number of reports have described the correlation of Doppler scan-derived velocities and recurrent arterial stenosis after intra-arterial endoluminal stenting. After both carotid and RA stenting, many reports indicate the velocity criteria for native artery disease overestimate the presence of significant stenosis after endoluminal stenting.[12-21] The most common explanation offered for this observation is a decrease in the arterial wall compliance after stenting. This explanation presumes that the energy that dilates the unstented vessel is expended as increased blood velocity within the noncompliant stent.[12] Contrary to this presumed increase in blood flow velocity, decreased vessel wall compliance would be expected to increase the propagation speed of the ultrasound scan in the stent. However, this increased propagation speed should not affect the blood flow velocity or its measurement because the latter is based on the Doppler scan shifted signal from moving blood elements. This alternative view is supported by Doppler scan flow wire measurements with and without endoluminal stents.[22,23] Moreover, despite the compliance changes associated with RA bypass and endarterectomy, we have observed a high correlation between native RDS criteria for intraoperative assessment and postoperative surveillance compared with cut-film angiography.[2]

A potential limitation of this and many other studies is the accuracy of the most common reference standard—DSA. Angiography provides a two-dimensional image of a three-dimensional structure. This limitation has been best demonstrated by studies comparing intravascular ultrasound scan and stenting in the coronary circulation.[24-27] In addition, angiography provides a static anatomic image without physiologic flow data. In the case of temporal DSA, the digitally subtracted anatomic image of a diseased vessel after PTAS can overestimate improvement compared with physiologic assessment. This is especially true when postprocessing uses peak opacification and pixel shift functions.[28] Moreover, the influence of an endoluminal stent on temporal digital subtraction techniques of luminal measurement has been incompletely studied. Although the RA motion with respiratory arrest is much less than seen in the coronary circulation, retrospective misregistration artifacts likely occur and may overestimate lumen diameters.

The experience described herein suggests the RDS criteria for recurrent stenosis after PTAS are similar to those for native RA disease. This view is shared by other authors but certainly not all. Rocha-Singh et al[29] in the Renal Artery Stenting with Noninvasive Duplex Ultrasound Follow-up (Renaissance) trial completed RDS in 93 subjects providing comparative DSA from 36 within PTAS.[29] Concordance between RDS PSV ≥2.25 milliseconds or renal aortic ration (RAR) ≥3.5 and ≥70% angiographic restenosis was 87%. By contrast, Chi et al[6] reported on 67 consecutive patients after PTAS with suspected restenosis based on native RA criteria of PSV ≥2.0 milliseconds and RAR ≥3.5. Native RDS criteria were associated with angiographic narrowing in only 46% of patients. Compared with selective renal angiography using digital subtraction with anteroposterior and left anterior views, ROC curves indicated that PSV ≥3.95 milliseconds or RAR ≥5.1 were the most predictive of angiographic ≥70% restenosis. It should be noted that these authors did not report on ROC curves for unstented atherosclerotic RA lesions; however, native RDS criteria for these lesions correlated with angiographic narrowing in only 55% of patients.

Many reports of RDS for both native disease and restenosis after PTAS cite RAR as a discriminating criteria for significant RA narrowing.[6,30-32] The rationale first provided for RAR was that RA velocities reflected aortic velocities in combination with increased velocities associated with narrowing in the RA.[33] However, data from both population-based studies and patient management have demonstrated no correlation between aortic and RA PSV.[1] Rather, the association between RA stenosis and RDS resides entirely with PSV. Consequently, the RAR term should be viewed as a spurious correlation rather than a discriminating criteria for both native stenosis and restenosis after PTAS.[1]

All studies published to date suffer from the well-recognized limitation of verification bias. Studies to date have performed the reference standard procedure (ie, digital subtraction and/or computerized tomographic angiography) based on the result of RDS.[5,6] When the reference standard procedure depends on the test of investigation, a reliable estimate of diagnostic accuracy is precluded. To obtain valid accuracy estimates of RDS criteria, all subjects should undergo both RDS and angiography at predefined intervals regardless of the RDS result. One or more of the ongoing randomized clinical trials comparing PTAS with best medical management may provide prospective cohort studies of both RDS and angiography. In addition, the authors have begun a prospective study that compares RDS, intravascular ultrasound scan, pullout pressures, and DSA before and after PTAS for RVD.

Although our experience supports the notion that native RA RDS criteria have use after PTAS, our report has a number of other limitations. In addition to verification bias, physiologic assessment by arterial pressure measurements was obtained only at completion of primary PTAS and after re-angioplasty for restenosis. Pressure measures were not routinely obtained before RA intervention. In addition, angiography was only performed when RDS criteria for restenosis was accompanied by worsening blood pressure control or renal insufficiency. Angiography was not repeated if the initial intervention was not associated with blood pressure/renal function benefit or clinical benefit was maintained despite a positive RDS result. This latter practice may have reduced the number of false-positive RDS studies.

In conclusion, this experience suggests that duplex sonography scan has use after RA angioplasty and stenting to define RA patency with and without restenosis. Native criteria for restenosis compare favorably with optimal RDS criteria for restenosis estimated by ROC curves.

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## AUTHOR CONTRIBUTIONS

Conception and design: KH, TC
Analysis and interpretation: KH, SF
Data collection: SF, RD
Writing the article: KH, SF
Critical revision of the article: KH, CG
Final approval of the article: KH
Statistical analysis: TC
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Overall responsibility: KH

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## DISCUSSION

**Dennis Bandyk**, (*Tampa, Fla*). The vascular surgery group from Wake Forrest University are experts in renal duplex ultrasound testing, and thus their recommendation of interpretation criteria after renal artery stenting is welcomed. This retrospective analysis of renal artery hemodynamics following stent angioplasty concluded similar duplex criteria can be used to estimate stent stenosis severity. The diagnostic accuracy of duplex testing was evaluated by receiver-operator curve (ROC) analysis and optimal velocity spectra criteria to detect a >60% stent stenosis were selected based on the highest accuracy and positive predictive values. The peak systolic velocity >2.5 m/s was associated with an accuracy of 83% and positive predictive value of 87%.

The threshold velocity criteria to diagnose renal stent stenosis depend on the goal of testing. If the goal is to all stenosis, then criteria of a peak systolic velocity of 1.8 m/s, which yielding the highest sensitivity would be used. But if the goal of testing is to identify high-grade stent stenosis, which should be considered for re-intervention or considered a "failed" intervention than values yielding the highest positive predictive value should be used.

This study had strengths and weaknesses. A study strength was that duplex studies were obtained prior to and immediately after renal stenting and correlated with measured renal artery pressure gradients in the majority of patients. Study weaknesses included a small patient series and the absence of hemodynamic information on the functional impact of an identified stenosis on hilar artery flow. I was somewhat surprised the group does like the renal-aortic ratio as a diagnostic parameter (although measurement of peak aorta velocity was included in the renal duplex scan protocol, especially since the recent study by Mohabbat and associates (J Vasc Surg April 2009) recommended an RAR of 4.5 because of its high (97%) diagnostic accuracy. After reading this article, I wondered if the "best" diagnostic criteria for stent stenosis requiring consideration for reintervention in an individual patient should be the renal PSV prior to intervention - in this study, the renal stenosis mean renal PSV prior to stenting was 2.75 m/s - very similar to the recommendation of 250 cm/s. Our group uses a renal artery stent PSV of >3.0 m/s as the threshold for consideration of reintervention.

I have two questions for the authors: (1) Was the goal of duplex testing to detect stent stenosis or to screen for a clinically important stenosis, which would then guide decision-making for additional testing or when to reintervene? and (2) Why not utilize the RAR or assessment hilar artery velocity spectra parameters (acceleration time, peak velocity) to determine the functional significance of an identified renal artery stent stenosis. The use of two diagnostic criteria would improve the positive predictive value of renal duplex testing.

**Dr Shawn H. Fleming.** I think that in answer to the first question, our goal for deciding on who to reintervene on, we did not just use duplex criteria alone, we identified patients with greater than 1.8 m/s as patients that potentially had restenosis but in order to get an intervention, they also had to have demonstrated clinical decline in either worsening hypertension or worsening renal function. In addition to this, any patient can get reintervened on also had to have responded clinically to prior intervention, so while we use this cut point to define who may have restenosis, we combine it with the clinical picture to decide who gets reintervened on. In that sense, we feel that using a study with high sensitivity would be best.

In response to your second question, at Wake Forest, it has not been our practice to use the renal-aortic ration as a determinant of stenosis. This practice goes back to studies done at our institution in the early 90s, where it was found that aortic velocities tend to be sporadic and not particularly predictive of stenosis. We have found that PSV alone has been a more accurate determinant of RAS.